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IN THE CIRCUIT COURT FOR
HOWARD COUNTY, MARYLAND

C.A. NO.
C-13-CV-19-000501

HOWARD COUNTY, MARYLAND
3430 Court House Drive
Ellicott City, Maryland 21043
A Body Corporate and Politic

Plaintiff,

v.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

PURDUE PHARMA, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

THE PURDUE FREDERICK COMPANY INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

TEVA PHARMACEUTICALS USA, INC.
190 Horsham Road
North Wales, PA 19454

CEPHALON, INC.
41 Moores Road
Frazer, PA 19355

JOHNSON & JOHNSON
1 Johnson And Johnson Plaza
New Brunswick, NJ 08933

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN

COMPLAINT

(Jury Trial Demanded)

PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
600 N 2nd Street, Suite 401
Harrisburg, Pennsylvania 17101-1071

ENDO HEALTH SOLUTIONS INC.
1400 Atwater Drive
Malvern, PA 19355

ENDO PHARMACEUTICALS, INC.
The Corporation Trust Incorporated
300 E. Lombard Street
Baltimore, MD 21202
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110

INSYS THERAPEUTICS
133 S Spectrum Blvd #100
Chandler, AZ 85286

JOHN N. KAPOOR
121 Stone Gate Road
Lake Forest, IL 60045-2434

CARDINAL HEALTH INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

MALLINCKRODT LLC
c/o The Corporation Trust, Incorporated
2405 York Road
Suite 201
Lutherville Timonium, MD 21093

MALLINCKRODT PLC
675 McDonnell Blvd.
St. Louis, MO 63042

SPECGX LLC
385 Marshall Avenue
Webster Groves, MO
63119

MALLINCKRODT BRAND
PHARMACEUTICALS, INC.
675 McDonnell Blv.
St. Louis, MO 63042

MCKESSON CORPORATION
c/o CSC-Lawyers Incorporating
Service Company
7 Saint Paul Street Suite 820
Baltimore, MD 21202

AMERISOURCEBERGEN
DRUG CORPORATION
2405 York Road Suite 201
Lutherville Timonium, MD 21093

WALGREEN CO.
c/o CSC-Lawyers Incorporating
Service Company
7 Saint Paul Street Suite 820
Baltimore, MD 21202

RITE AID CORPORATION
The Corporation Trust,
Incorporated
2405 York Road, Suite 201
Lutherville Timonium, MD
21093-2264

AND

RITE AID OF MARYLAND,
INC.
The Corporation Trust,
Incorporated
2405 York Road Suite 201
Lutherville Timonium, MD

21093-2264

Defendants.

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I. PRELIMINARY STATEMENT

1. Plaintiff, Howard County, Maryland ("the County"), like many other communities across the country, is struggling with an opioid crisis. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis began with a corporate business plan. It started with a decision by Purdue Pharma L.P., and its corporate family (collectively, "Purdue"), to promote opioids deceptively and illegally to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. Unfortunately, Purdue's strategies were quickly adopted by other pharmaceutical manufacturers: Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Mallinckrodt plc; Mallinckrodt Brand Pharmaceutical, Inc.; Mallinckrodt LLC; and SpecGx LLC (collectively with Purdue, "Manufacturing Defendants"), all of whom, along with Insys Therapeutics, Inc. and John N. Kapoor[1], used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[2] In addition, the Manufacturing Defendants, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Co.; Rite Aid Corporation; and Rite Aid of Maryland, Inc. (collectively, "Distributor Defendants") failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders (e.g., orders of unusual size, orders deviating substantially from a

[1] Defendants Insys Therapeutics, Inc. and John N. Kapoor are discussed separately from the other manufacturing defendants because their conduct, as described in Section IV. F., was, in many respects, different than the conduct of the other manufacturing defendants described herein.

[2] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

normal pattern, and orders of unusual frequency). As a direct consequence, the rampant use, overuse, and abuse of opioids has overwhelmed much of the country, including Howard County and its residents.

2. Howard County brings this action to redress Defendants' campaign of unfairly, deceptively, and fraudulently marketing, promoting, and distributing opioids.

3. Manufacturing Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Subsys, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

4. Distributor Defendants Cardinal Health, Inc.; McKesson Corporation d/b/a McKesson Drug Company; AmerisourceBergen Drug Corporation; Walgreens Co.; Rite Aid Corporation; and Rite Aid of Maryland, Inc. distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and in Howard County.

5. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. Opioids can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience severe and often prolonged withdrawal symptoms. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain) — requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

6. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain — where brief use

limited the need for escalating doses and the risk of addiction — or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

7. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by Teva, Janssen, Endo, Mallinckrodt, and, more recently, Insys, began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, these Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.From the day they made the opioids to the day the medicines were consumed in our communities, including Howard County, the Manufacturing Defendants and Defendant Insys had control over the information that they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing more and more of their products by arguing, among other things, that they fail to meet the standard of care if their patients continue to complain of pain, the Manufacturing Defendants created a population of addicted patients, including in Howard County, who sought opioids at never-before-seen rates. Defendant Insys exploited this expanding market for opioids as it aimed to sell more of its opioid, Subsys.

8. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids and against diversion, and who instead have actively sought to evade such controls. Defendants have

contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

9. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care setting struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

10. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Howard County, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[3] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who can no longer legally acquire or simply cannot afford prescription opioids.

11. This explosion in opioid use and the concurrent explosion in Defendants' profits have come at the expense of patients and have caused ongoing harm and damages to the County. As the then CDC director concluded in 2016: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.[4]

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[3] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

[4] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

12. A substantial amount of the costs associated with opioid use disorder is borne by government entities. The necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care, among others.

13. Accordingly, Howard County brings this action to hold Defendants accountable for their conduct and to seek damages, abatement, and any other injunctive and equitable relief within this Court's powers to redress and halt Defendants' unfair, deceptive, and unlawful practices.

II. PARTIES

A. Plaintiff

14. Howard County, Maryland is a charter~~ed~~ county of the State of Maryland established under Article XI-A of the State Constitution with powers conferred upon it by, *inter alia*, Titles 9 and 10 of the Local Government Article of the Annotated Code of Maryland. Pursuant to Md. Loc. Gov't. Code Ann., § 9-201(2) and Section 101 of the Howard County Charter, the County, as a charter county, has the capacity to sue.

15. The County has a population of 287,085, and the County seat is Ellicott City. The County provides many services for its residents, including public health, public assistance, law enforcement, emergency care, and services for families and children. For its employees, the County also funds its own health insurance and workers' compensation programs. From January 1, 2011 until January 1, 2018, County funded health insurance and workers compensation plans spent over $1.3 million on opioid prescriptions for County employees.

16. The County brings this action on its own behalf and in the public interest.

B. Defendants

17. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Together, these entities are referred to herein as "Purdue." In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids.

18. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in the County.[5] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

19. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States, including Howard County. Teva USA also sells generic opioids throughout the United States and Howard County. In August 2016, Teva Pharmaceutical Industries Ltd., which is based in Israel and is Teva USA's parent company, acquired Allergan plc, including the generic opioid business that Allergan had previously operated. These parties are collectively referred to herein as "Teva."

[5] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

20. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the United States and in the County. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, Gabitril and Provigil, and agreed to pay $425 million.

21. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit.

22. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. One code of conduct on Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted

on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

23. Similarly, the "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

24. J&J also asserts control over Janssen through its management team. According to Janssen's website, the "leadership team that guides Janssen" contains several J&J executives.[6]

25. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. In addition, J&J made payments to front groups, discussed herein, who

[6] Members of Janssen's "leadership team" include Joaquin Duato, Vice Chairman of the Executive Committee, Johnson & Johnson, Paul Stoffels, M.D. Vice Chairman of the Executive Committee, Chief Scientific Officer, Johnson & Johnson, Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson, Jeff Steinhorn, Chief Information Officer, Pharmaceuticals, Head of Enterprise Functions, Johnson & Johnson Technology, and Scott White, Company Group Chairman, North American Pharmaceuticals, Johnson & Johnson. https://www.janssen.com/about/our-leadership. (last visited on September 18, 2018)

perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[7] Janssen and J&J are collectively referred to herein as "Janssen."

26. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Howard County, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

27. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

28. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in Howard County. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Howard County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would

[7] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, n. 23 ("Payments from Janssen include payments from Johnson & Johnson, Health Care Systems, Inc.").

stop marketing and selling a reformulated version of Opana ER that it had marketed as an abuse-deterrent.

29. Mallinckrodt, plc, is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC, was a wholly-owned subsidiary of Covidien plc. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt plc. Defendant SpecGx, LLC, is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt, LLC. Mallinckrodt, plc, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals, and SpecGx, LLC, are referred to as "Mallinckrodt."

30. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

31. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. In 2015, Mallinckrodt estimated, based on IMS Health data, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[8] In 2017, Mallinckrodt paid a $35 million fine to the Department of Justice for its failure to report suspicious orders of its opioids.[9]

32. Collectively, Purdue, Teva, Janssen, Endo, and Mallinckrodt are referred to herein as "Manufacturing Defendants."

33. Insys Therapeutics, Inc. ("Defendant Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys' principal product and source of revenue is Subsys, a transmucosal immediate-release formulation ("TIRF") of fentanyl, contained in a single-dose spray device intended for oral sublingual administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain. Insys promotes, sells, and distributes Subsys throughout the United States and in Howard County.

34. John N. Kapoor is a resident of Lake Forest, Illinois, and was the founder and owner of Insys. He held various executive positions at Insys including Chairman of the Board of Directors and CEO. In 2013, *Forbes* Magazine listed him as a billionaire following the success of Insys' initial public offering. In 2017, Kapoor was arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies by the Office of the United States Attorney

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[8] https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm.

[9] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

for the District of Massachusetts. At all times, he personally directed the activities of Insys, including, upon information and belief, the payment of fraudulent kickbacks to prescribers, and directed the misrepresentations made to third party payors to obtain off-label coverage of Subsys, including, upon information and belief, in Howard County.

35. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country, including in Howard County. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

36. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Howard County. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

37. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Howard County. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

38. Cardinal, McKesson and AmerisourceBergen are, at times, collectively referred to herein as "The Big Three."

39. Walgreen Co. ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in Howard County and throughout the country, including in Howard County. Walgreens is headquartered in Deerfield, Illinois, and has distribution centers across the country which distribute medications, including opioids, to various states, including Maryland. Walgreens is registered to do business in Maryland under the name Walgreen Co.

40. Defendant Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid, through its various DEA registrant subsidiaries and affiliated entities, distributed prescription opioids throughout the United States, including in Howard County. Defendant Rite Aid of Maryland, Inc. is a Maryland corporation with its principal office located in Lutherville Timonium, Maryland. Rite Aid Corporation and Rite Aid of Maryland, Inc. are collectively referred to herein as "Rite Aid." At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States and in Howard County. According to its website, Rite Aid operates 3,871 retail stores with pharmacies, including 121 retail locations in the state of Maryland, three of which operate within the County.

41. Cardinal, McKesson, AmerisourceBergen, Walgreens, and Rite Aid are at times collectively referred to herein as "Distributor Defendants."

42. The Distributor Defendants dominate the wholesale distribution market, including in Howard County. In order to increase their revenue, increase their profits, and grow their share of the prescription painkiller market, each of the Distribution Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their fundamental duty under Maryland and federal statutes, and Maryland common law, to detect,

report, and refuse to ship suspicious orders of opioids in order to prevent diversion of these dangerous drugs for non-medical purposes. Each has been cited and fined by the DEA and/or DOJ for failing to maintain effective controls against diversion. This unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Howard County.

III. JURISDICTION AND VENUE

43. The amount of this claim exceeds $75,000.

44. The venue for this claim is proper in the Circuit Court for Howard County.

45. Venue as to each Defendant is proper in this Court because each of the Defendants carries on regular business in Howard County and/or the causes of action alleged in this Complaint arose in Howard County.

46. This Court has subject matter jurisdiction over this action.

47. This Court has personal jurisdiction over Manufacturing Defendants, Defendant Insys, and Distributor Defendants pursuant to Md. Code Ann., Cts. & Jud. Proc. § 6-103 because they transact business in the state of Maryland, contract to supply goods and manufactured products in the state of Maryland, carry on a continuous and systematic part of their general businesses within Howard County, have transacted substantial business with Howard County entities and residents, and have caused grave harm in Howard County as a result.

48. This Court has personal jurisdiction over Defendant Kapoor because he personally directed the commission of tortious acts in Howard County, including, upon information and belief, payments to prescribers in Howard County to induce them to prescribe Subsys, and misrepresentations to third party payors to obtain off-label coverage of Subsys and increase prescribing and use of Subsys in Howard County.

49. The County does not allege any federal cause of action, and to the extent that any pleading allegedly can be interpreted as stating any claim arising under federal law, any and all such federal claims are expressly disavowed. No federal question, substantial or otherwise, arises from the County's pleadings or is stated in said pleadings. Every claim and pleading by the County in this case can be adjudicated without resolving any federal question; therefore, federal questions are not raised and are certainly not necessarily resolved. Moreover, even assuming there is a federal question, which is denied, no such federal question is substantial to the federal system as a whole See Gunn v. Minton, 568 U.S. 251 (2013). To the extent federal enforcement actions are discussed in this complaint, these pleadings do not state any federal claim or raise any federal question but rather are factual allegations showing Defendants' mens rea and the course of Defendants' malfeasance as factual matter. No federal question is substantial, is raised, or is necessarily adjudicated here because Maryland statutory and regulatory requirements mirror federal duties with regard to controlled substances, and the County exclusively is relying on the state statutes, the state regulations, state common law, and County law, rather than on any federal law, regulation or standard. The County makes no claim, and expressly disavows any alleged claim, against or directed to the United States or any agency thereof or any officer (or any person acting under that officer) of the United States or any agency thereof, in an official or individual capacity, for or relating to any act under color of such office; including without limitation, the County denies seeking, and expressly disavows, any recovery arising from McKesson Corporation's federal contract to supply prescription medication. See 28 U.S.C. § 1442. The statements in this paragraph are controlling notwithstanding anything alleged to the contrary.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

50. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Manufacturing Defendants have sought to successfully turn that consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

51. Through marketing that was as pervasive as it was deceptive, Manufacturing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven, undermining general warnings in labels and elsewhere. Purdue's sales representatives, in particular, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that "old views" of opioid addiction were untrue, and that "appropriate patients" would not become addicted. These themes were repeated by sales representatives from other Manufacturing Defendants.

52. The Manufacturing Defendants blanketed the medical community with their misleading and deceptive misinformation campaign to change the narrative regarding the appropriate use of opioid medications and increase their profits. They enlisted trusted doctors, professional associations, and patient groups to disseminate their misrepresentations overstating the benefits of opioid use for chronic pain conditions and downplaying the risks of such use. As discussed more fully below, these doctors and groups appeared to be independent, but were funded and controlled by the Manufacturing Defendants to distort the public's and medical communities' perception of the risks, benefits, efficacy, and superiority of opioids to treat chronic pain. Misleading and deceptive messages were disseminated through seminars, physician Continuing

Medical Education programs, speaker programs, websites, patient guides, and "scientific" and other publications given to doctors and stacked in patient waiting rooms.

53. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturing Defendants not only deceptively marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), [10]who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' misleading marketing claims.

54. Manufacturing Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

A. Manufacturing Defendants Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

55. Manufacturing Defendants, and Defendant Insys, rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. These visits frequently coincide with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Purdue's former Vice President of Marketing, Russ Gasdia, acknowledged the utility of a Purdue

[10] For example, in 2013, Purdue sought to identify Key Opinion Leaders ("KOLs") to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue's largest growth area.

sales representative as "someone [prescribers] can look to for the information they need to make prescribing decisions."

56. Not surprisingly, all of the Manufacturing Defendants' and Defendant Insys' sales representatives visited prescribers in Howard County. Publicly available data shows that these Defendants' sales representatives visited Howard County prescribers at least 346 times between the third quarter of 2013 and the end of 2016.[11] This number understates the amount of "detailing" by each of the sales representatives for Manufacturing Defendants and Defendant Insys, as it only reflects visits in which some sort of payment was provided to the prescriber.

57. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[12] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

58. To ensure that sales representatives delivered the desired messages to prescribers, Manufacturing Defendants and Defendant Insys, directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide

[11] https://openpaymentsdata.cms.gov

[12] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

through national and regional sales representative training. Thus, upon information and belief,[13] their sales forces in Maryland and Howard County carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

59. Manufacturing Defendants and Defendant Insys were aware of the strength of in-person marketing. The effects of sales calls on prescribers' behavior are well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[14] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization.[15] An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.[16]

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[13] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Howard County in the same manner as elsewhere.

[14] Ian Larkin et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing, 317 J. Am. Med. Ass'n 1785 (2017).

[15] Berdent ER, et al. Information, Marketing and Pricing In the US Antiulcer Drug Market. Amer. Econ Rev 1995, 85:101-105.

[16] Wazana A. Physicians And The Pharmaceutical Industry: Is A Gift Ever Just A Gift? JAMA 2000,283:373-80.

60. Manufacturing Defendants also used "key opinion leaders" ("KOLs") — 0experts in the field who were especially influential because of their reputations and seeming objectivity — to deliver paid talks and continuing medical education programs "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Manufacturing Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the Defendants' messages regarding the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[17]

61. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Manufacturing Defendants exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain by overstating their benefits, and understating their risks. In many instances, Manufacturing Defendants distributed these publications to prescribers or posted them on their websites.

[17] Catan, Thomas, and Perez Evan, "A Pain-Drug Champion Has Second Thoughts," The Wall Street Journal, December 17, 2017, available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

62. The FDA does not regulate all of the conduct in which the Manufacturing Defendants and Defendant Insys engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue and, upon information and belief, the other Manufacturing Defendants and Defendant Insys, marketed their drugs. The FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate the marketing messages or scripts relied on by Manufacturing Defendants' sales representatives or marketing funneled through third-parties. Upon information and belief, all of the messages described below were disseminated to Howard County prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources.

i. Minimizing or mischaracterizing the risk of addiction

63. To convince prescribers and patients that opioids should be widely prescribed for long term use of chronic pain conditions and increase the market for and sales of opioids, Manufacturing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted;, (2) patients at greatest risk of addiction could be identified, (3) all other patients could safely be prescribed opioids;, and (4) even high-risk patients could be prescribed opioids if closely managed.

64. Upon information and belief, sales representatives regularly omitted from their sales conversations with prescribers in Howard County any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

65. Manufacturing Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to these Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. Manufacturing Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain; upon information and belief, the same message was delivered to prescribers in Howard County. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction.

66. In addition, upon information and belief, Manufacturing Defendants' sales representatives also failed to disclose to prescribers in Howard County the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

67. Manufacturing Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa —under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through prescribed oral use. According to briefing

materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

68. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, to prescribers in Howard County.

69. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"). Purdue was APF's second-biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill.

70. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide*. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

71. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue

copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[18]

72. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013 — a fact notably omitted from the site.

73. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

74. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

75. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are

[18] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).

rarely addictive when used properly for the management of chronic pain." This guide is still available online.

76. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

77. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[19]

78. Among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[20] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

79. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused

[19]https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php.

[20] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!*. The false claims and misrepresentations in this book include the following statements:

> a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
>
> b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
>
> c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
>
> d. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
>
> e. "[I]n our experience, the issue of tolerance is overblown."
>
> f. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
>
> g. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
>
> h. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
>
> i. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

This book is still available online in Howard County and elsewhere.

80. Manufacturing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40%, of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk [] of .. . addiction" — "even at recommended doses" — of all opioids.[21] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[22] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[23] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

81. Furthermore, to the extent Defendants' labels mentioned the risks of addiction or abuse, Defendants' misleading and deceptive marketing minimized and trivialized these risks, reassuring physicians that they could prescribe opioids for long-term use because their patients were unlikely to become addicted.

ii. Manufacturing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

82. Manufacturing Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a

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[21] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[22] CDC Guideline at 2.

[23] *Id.* at 21.

concept invented by Dr. David Haddox, a future Purdue paid speaker and executive, and Dr. David E. Weissman. The concept was used to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. By disseminating misleading information regarding pseudoaddiction, Defendants acted with the sole purpose of increasing their profits at the expense of patients.

83. Purdue, through its unbranded imprint *Partners Against Pain*[24], promoted pseudoaddiction through at least 2013 on its website.

84. The Federation of State Medical Boards ("FSMB"), an national organization representing state medical boards, including the Maryland Board of Physicians, finances opioid- and pain-specific programs through grants from Manufacturing Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

85. The Manufacturing Defendants sponsored the publication of *Responsible Opioid Prescribing* by. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies

[24] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in Howard County.

86. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

87. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

88. Manufacturing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturing Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

89. The FAQs section of pain-topics.org, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'" [25]

[25] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance.

90. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[26] and that physicians should "reassess [] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[27]

iii. Overstating the efficacy of screening tools

91. Manufacturing Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturing Defendants undermined general concerns or warnings regarding addiction in drug labels and elsewhere by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

92. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Purdue aimed them at general practitioners and family doctors who lack the time and expertise to

[26] CDC Guideline at 13.

[27] *Id.* at 25.

closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

93. Upon information and belief, these Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors in Howard County.

94. On information and belief, Purdue sales representatives in Howard County also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

95. Manufacturing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to Howard County prescribers.

96. For example, Purdue sponsored a 2011 CME program titled *Managing Patients' Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

97. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and

other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

98. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number of talks—with very different messages from non-Purdue talks—at each CPDD conference. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids to others without causing addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from Howard County, attended these conferences.

99. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

100. A 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

101. Manufacturing Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As these Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

102. Further, the 2016 CDC Guideline confirms the falsity of Manufacturing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools or patient contracts — "for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[28]

B. Manufacturing Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use In Order to Increase their Profits

i. Mischaracterizing the benefits and evidence for long-term use

103. To convince prescribers and patients that opioids should be used to treat chronic pain to increase the number of opioid prescriptions and their profits, Manufacturing Defendants had to persuade the medical community of a significant upside to long-term opioid use. Assessing existing evidence, the 2016 CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[29] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[30] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support

[28] CDC Guideline at 28 (emphasis added).

[29] *Id.* at 10.

[30] *Id.* at 9.

long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[31] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

104. Upon information and belief, Manufacturing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

105. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Manufacturing Defendants. Upon information and belief, Manufacturing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

106. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturing Defendants in securing

[31] Letter from Janet Woodcock, M.D., Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain, but who frequently treat patients who suffer from chronic pain, such as the elderly. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

107. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

108. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

109. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

110. Manufacturing Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions, and pose little risk to patients. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results… should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[32] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[33] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

111. Teva deceptively marketed its opioids, Actiq and Fentora, for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

112. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly

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[32] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[33] *Id.*

prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

113. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[34] by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

114. For example: Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

115. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

[34] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

116. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain. The FDA does not regulate or approve journal publications sponsored by drug manufacturers, such as the Special Report.

117. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

118. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

ii. Overstating opioids' effect on patients' function and quality of life

119. Upon information and belief, Manufacturing Defendants also claimed to Howard County doctors—without evidence—that long-term opioid use would help patients resume their lives and jobs.

120. Manufacturing Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in Howard, reinforced this message.

The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

121. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

122. Defendant Mallinckrodt's website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[35] Additional illustrative examples are described below:

- Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009)—which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation,

[35] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

- Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

- Purdue and Teva sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

- Endo's NIPC website, painknowledge.com, claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

- Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

123. Likewise, Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

124. One pain specialist observed, "Opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these

patients are unable to function normally."[36] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[37] Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later. [38]

125. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[39] The FDA and other federal agencies have made this clear for years. [40] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[41] The CDC Guideline concluded that "[w]hile benefits for pain

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[36] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[37] *Id.*

[38] Jeffrey A. White, et al., The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[39] CDC Guidelines. at 20.

[40] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[41] CDC Guideline at 2.

relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[42] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[43]

126. In materials Manufacturing Defendants produced, sponsored, or controlled, Manufacturing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

iii. Omitting or mischaracterizing adverse effects of opioids

127. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturing Defendants routinely ignored the risks of hyperalgesia, a known serious risk associated with chronic opioid analgesic therapy, in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

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[42] *Id* at 18.

[43] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

128. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[44] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

129. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

130. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

131. Manufacturing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults*

[44] The higher figure reflects deaths from all causes.

(Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

132. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[45] Again, Manufacturing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%.[46] Another study of an estimated 440 million visits for back pain over a period from 1999 to 2010 found that the use of NSAIDs fell from 36.9% to 24.5%, while use of narcotics increased from 19.3% to 29.1.%.[47] The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.[48]

C. Manufacturing Defendants Continued to Tell Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

133. Manufacturing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high

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[45] Meredith Noble M, *et al*., *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010.).

[46] John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

[47] *Id.*

[48] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.

doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribing opioids for more frequent dosing.

134. Purdue-sponsored publications and CMEs available, upon information and belief, in Howard County also misleadingly suggested that higher opioid doses carried no added risk.

135. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

136. *A Policymaker's Guide*, the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary" but did not disclose the risks from high dose opioids.

137. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

138. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased.. . . You won't 'run out' of pain relief."

139. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

140. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[49] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[50]

D. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief When Purdue Knew That, For Many Patients, It did Not

141. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

142. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed

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[49] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[50] CDC Guideline at 16.

to prescribers that the solution to end-of-dose failure is not more frequent dosing but higher doses—which pose greater risks.

143. OxyContin has been FDA-approved for twice-daily —"Q12"—dosing frequency since its debut in 1996. It was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar.

144. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end-of-dose failure"—*i.e.,* little or no pain relief at the end of the dosing period.

145. Moreover, Purdue itself long has known, dating to its development of OxyContin that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers — "rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.[51]

[51] Harriet Ryan, "' *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los

146. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[52] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

147. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.,* every 8 hours) because 12-hour dosing was "a significant competitive advantage," among other reasons.[53] Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse—a misrepresentation made upon information and belief, in Howard County.

148. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to

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Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

[52] *Id.*

[53] *Id.*; http://documents.latimes.com/purdue-response-fda-2004/.

prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.

149. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[54]

E. Purdue and Endo Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

150. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids— thereby further exacerbating the opioid epidemic in Howard County and elsewhere.

i. <u>Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER</u>

[54] CDC Guideline at 16.

151. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

152. It is unlikely to be a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

153. Upon information and belief, Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis to prescribers in Howard County.

154. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue detailers:

a. claimed that Purdue's ADF opioids *prevent* tampering and that its ADF products could not be crushed or snorted.

b. claimed that Purdue's ADF opioids *reduce* opioid abuse and diversion.

c. asserted or suggested that Purdue's ADF opioids are "safer" than other opioids.

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or

misuse.

155. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

156. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[55] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected[56].

157. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

158. A 2013 article, presented by Purdue employees based on the review of data from poison control centers, ignored important negative findings while concluding that ADF OxyContin can reduce abuse. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to

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[55] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

[56] PMRS Citizens Petition.

opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

159. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[57] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death." [58]

160. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[59] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

161. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox,

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[57] CDC Guideline at 22. (emphasis added).

[58] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[59] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.[60]

ii. Endo's deceptive marketing of reformulated Opana ER

162. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent formulations, also made abuse deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

163. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

164. In August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for

[60] Jacobs, Harrison, There is a Big Problem With the Government's Plan to Stop the Drug-Overdose Epidemic, Business Insider, March 16, 2016, available at https://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

165. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[61] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[62]

166. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[63]

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[61] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[62] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[63] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

167. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

168. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"), which can cause kidney failure.[64] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

169. Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in Maryland and Howard County that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously

[64] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

and, if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

170. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

171. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[65] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[66] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[67]

172. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on

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[65] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[66] *Id.*

[67] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally.

173. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

F. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

174. Insys' opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

175. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Teva's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[68] Prescribers must enroll in TIRF REMS before writing a prescription for Subsys.

[68] Press Release, FDA, FDA Approves Shared System REMS for TIRF Products, December 29, 2011.

176. Since its launch, Subsys has been an extremely expensive medication, and Insys has increased its prices every year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

177. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . meaning no reimbursement would be due."[69]

178. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims.[70] Thus, even when Insys sales representatives were able to persuade prescribers to prescribe Subsys for non-cancer chronic pain conditions, their sales were thwarted by the prior-authorization requirements.

179. Defendant Kapoor and other executives "planned and created" a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys prescriptions.[71]

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[69] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

[70] Lopez, German, *Want to Understand How Big Pharma Helped Create the Opioid Epidemic? Read This Report*, Vox, September 6, 2017, available at https://www.vox.com/policy-and-politics/2017/9/6/16262456/claire-mccaskill-insys-opioid-epidemic.

[71] *United States v. Michael Babich, et al.*, 1:16-cr-10343-ABD, Second Superseding Indictment, p. 16, Doc#419 (D. Mass. September 11, 2018) ("Second Superseding Indictment").

This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.[72]

180. According to the Congressional Staff Report, employees of the IRC received large financial incentives and pressure from management, which included group and individual bonuses, to increase the number of Subsys authorizations. To boost these numbers, IRC employees falsified medical histories of potential Subsys patients by asserting that the patient had a "cancer diagnosis regardless of the patient's history and regardless of whether the prescriber had prescribed Subsys for a prior diagnosis."[73]

181. After receiving scrutiny from the U.S. Department of Health and Pharmacy Benefit Managers ("PBMS"), Insys created a canned response to be used for questions regarding whether a patient had breakthrough cancer pain. The response that the Insys employees provided was "[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients [and] [t]he physician is treating the patient for their pain."[74] According to an affidavit filed in support of criminal charges against the head of the IRC, the employee script "deliberately omitted the word 'cancer' in order to mislead agents of insurers and PBMs."[75]

182. According to the 2018 Second Superseding Indictment of Kapoor and other executives, Defendant Kapoor tracked the ability of the IRC to obtain authorization for Subsys

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[72] German Lopez, *Want to Understand How Big Pharma Helped Create the Opioid Epidemic? Read This Report*, Vox, September 6, 2017.

[73] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

[74] *Id.*

[75] *Id.*

prescriptions and instructed IRC employees to make misrepresentations to third-party payors in order to obtain authorization for Subsys prescriptions. Indeed, the IRC manager told IRC employees that they needed to do a better job obtaining prescription approvals because "Dr. Kapoor's not happy, we have to get these approvals up." [76]In 2017, this manager plead guilty to conspiring to "defraud insurers."[77]

183. Subsys, has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys in 2016. Between 2013 and 2016, the value of Insys stock rose 296%.[78]

184. Since its launch in 2012, Insys has aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics and practices, such as the IRC. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treating those conditions. It implemented a kickback scheme wherein it paid prescribers for participating in fake speakers programs in exchange for prescribing Subsys more often and at ever increasing doses. And it defrauded insurance providers and health benefit payors into paying for improper prescriptions of Subsys. These fraudulent and misleading schemes had the effect of pushing Insys' highly potent and dangerous opioid onto patients who did not need it, further exacerbating the opioid epidemic.

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[76] *Id.*

[77] https://www.reuters.com/article/us-insys-court/ex-insys-employee-pleads-guilty-in-u-s-opioid-drug-probe-idUSKBN19A2MB.

[78] *Id.*

185. In addition, Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard.[79] The compensation structure weighed heavily on commissions, and rewarded sales reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[80]

186. The Insys "speaker program" was perhaps its most widespread and damaging scheme. According to a report by the Southern Investigative Reporting Foundation ("SIRF") a former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."[81]

187. Defendant Kapoor and other executives targeted prescribers for speaker program bribes and arranged for the payment of bribes and kickbacks to these prescribers including, upon information and belief, prescribers in Howard County. Defendant Kapoor personally participated in meetings to monitor the effectiveness of the bribes and kickbacks on prescribers. If Defendant Kapoor and other participating executives determined that Insys was not receiving a sufficient

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[79] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller, New York Times,* May 13, 2014.

[80] *Id.*

[81] Roddy Boyd, *Insys Therapeutics and the New 'Killing It'"*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

"return on investment" from the prescribers, they directed the reduction or discontinuance of the payments to the prescriber.[82]

188. In February 2014, Insys hired an outside consulting company, Compliance Implementation Services, LLC to review 15 speakers programs and to "provide assistance in meeting the on-going challenge in sustaining compliance" with the program.[83] After reviewing nine speaker programs, Compliance Implementation Services noticed several problems with the program. According to one summary, the company noticed that one presentation was "severely lacking in content delivery of safety information."[84] In another presentation, the company noted that "[s]afety information was not discussed at all during the presentation," and that there was "no clear disclosure to the attendees that he program was sponsored by Insys."[85] During another program, the Insys sales representative informed the attendees that the speaker would be providing information on Subsys, "[h]owever, there was no clear disclosure to the attendees."[86] Even more troubling, the speaker discussed Subsys for possible off-label use. According to the report, the discussion included "anecdotal information regarding patient with back pain for which Subsys was effective; however, it is unclear if the patient is an adult cancer patient."[87] Review by Compliance Implementation Services, LLC demonstrated further program deficiencies, such as that certain programs lacked a true educational purpose, and according to one program checklist, other than

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[82] Second Superseding Indictment, p. 15.

[83] Staff Report, Fueling an Epidemic, Part 4, *Inside the Insys Strategy for Boosting Fentanyl Sales*.

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] *Id.*

Compliance Implementation Services, LLC, and the Insys sales representative, "all attendees were from the speakers' office."[88]

189. Insys' sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

190. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In May of 2017, one of the doctors was sentenced to 20 years in prison.

191. In June of 2015, a nurse practitioner in Connecticut, described as the state's highest Medicare prescriber of narcotics, plead guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at a rate of approximately $1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted that she was receiving the speaker fees in exchange for writing prescriptions for Subsys.

192. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General, alleging that Insys paid doctors "speaking fees" to increase prescriptions of Subsys, among other allegations. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and employing an

[88] *Id.*

unconscionable scheme, including "speaking fees," whereby payments that were intended to be kickbacks were made to doctors to incentivize the doctor to prescribe Subsys. [89]

193. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of the Alabama prescribers discussed above to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients.

194. In August of 2016 the State of Illinois sued Insys for its deceptive and illegal practices. The complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The complaint explains that Insys categorized prescribers into deciles (D1-D10) according to the number of rapid onset opioids (ROOs) prescribed. The sales reps were instructed to call on the highest volume ROO prescribers more frequently than the low volume ROO prescribers, and encouraged to obtain the majority of their sales from one or two high volume prescribers.

195. The Illinois complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received a speaker "honorarium" ranging from $700 – $5,100 in addition to their meal. The prescribers were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the "speaker" and an Insys sales rep.

[89] In the Matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution, July 10, 2015.

196. In December of 2016, six Insys executives and managers were indicted by the United States Attorney's Office for the District of Massachusetts. The indictment alleged that the former Insys employees conspired to bribe prescribers, many of whom operated pain clinics, to induce them to prescribe Subsys. In exchange for bribes and kickbacks, the indictment states, the prescribers wrote large numbers of prescriptions for the patients, though most of them were not diagnosed with cancer. In announcing the indictments, the Special Agent in charge of the Boston Division of the FBI noted that this scheme "contributed to the growing opioid epidemic and placed profit before patient safety."[90]

197. In October 2017, federal prosecutors indicted and arrested Defendant Kapoor, adding him to the case filed against the other Insys executives in December 2016. Federal prosecutors filed the Second Superseding Indictment against Defendant Kapoor and the other Insys executives in September of 2018, narrowing the charges against them, but maintaining the allegations that Defendant Kapoor and others bribed prescribers and made misrepresentations to insurersto increase prescriptions of Subsys.

198. In September of 2018, the Attorney General of Maryland brought charges against Insys alleging that it committed thousands of violations of Maryland's Consumer Protection Act.[91] The complaint highlights the fact that the Insys speakers program as executed by Insys in Maryland was a "total sham."[92] Insys paid Maryland doctors to prescribe Subsys more and more frequently and in increasing doses to non-cancer patients. According to the Attorney General of Maryland,

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[90] *Press Release, United States Attorney's Office District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme, December 8, 2016.*

[91] *Consumer Protection Division, Office of the Attorney General v. Insys Therapeutics, Inc.*, Statement of Charges, CPD Case No.: 18-028-300480, September 6, 2018.

[92] *Id.*

more than 90 percent of Subsys prescriptions in Maryland were for patients whose conditions did not necessitate the use of the medicine. The Statement of Charges also confirms that the IRC was active in fraudulently obtaining authorizations for Subsys prescriptions in Maryland.

199. Insys' misleading marketing of Subsys as appropriate for non-cancer pain occurred in Howard County. Publicly available data shows that between the third quarter of 2013 and 2016 Insys sales representatives visited Howard County providers at least twenty times.[93] The majority of these visits were to doctors who specialized in pain medicine, not oncology. This number understates the number of visits Insys made to prescribers in Howard County, as it only reflects visits in which some sort of payment was provided to the prescriber and reported by Insys. The true amount of sales visits and calls that Insys made to Howard County prescribers is known only to Insys. Upon information and belief, Insys employed its fraudulent prior authorization scheme to seek approval of Howard County area doctors' prescriptions of Subsys.

G. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report and Terminate Suspicious Orders

200. The Manufacturing Defendants and Defendant Insys created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties.

201. For over a decade, as the Manufacturing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow

[93] https://openpaymentsdata.cms.gov.

their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

i. All Defendants Have a Duty to Report Suspicious Orders and Terminate those Orders Unless Due Diligence Disproves Their Suspicions.

202. Statutes, regulations, and the common law impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

203. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By supplying Howard County with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm to the County. As the supply of opioids and the evidence of addiction to and abuse of these drugs grew, manufacturers, distributors, and pharmacies were again reminded of both the nature and harms of opioid exposure and use.

204. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion of prescription opioids, to speak accurately and truthfully.

205. Third, Distributor Defendants, also referred to as wholesalers, violated their statutory obligations under Maryland law, which also incorporates the federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.* and its implementing regulations. COMAR

10.34.22.07(D)(1) (2016) (mandating that "a wholesale distributor shall: (1) operate in compliance with applicable federal, state, and local laws and regulations.");[94] *see also* COMAR 10.34.22.07(D)(3)(b) (2016) (stating that a wholesale distributor that deals in controlled substances shall "comply with all applicable federal, State, and local regulations").

206. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapses. The result is the scourge of addiction that has occurred.

207. The CSA requires manufacturers and distributors of Schedule II substances, like opioids, to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective

[94] Pursuant to COMAR10.34.22.02(B)(23)(b)(i) the definition of "wholesale distributor" includes a manufacturer.

controls against diversion of the controlled substances that they manufacturer or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

208. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider information including trends and rates of net disposal, an applicant's production cycle and current inventory position, total actual or estimated inventories of the class of drug and all substances manufactured from the class, trends in inventory accumulation, and other factors such as changes in the currently accepted medical use of substances, the economic and physical availability of raw materials, yield and sustainability issues, potential disruptions to production, and unforeseen emergencies.

209. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

210. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to passively process orders of controlled substances, counting their profits along the way. Rather, they "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id*. Suspicious orders include orders of unusual size, orders deviating substantially

from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

211. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

212. These requirements are adopted by and incorporated into Maryland law. As manufacturers and wholesale drug distributors of controlled substances, Defendants were required to register with the DEA. *See* COMAR 10.34.22.07(D)(3)(b) (2016); *See* 21 U.S.C. § 823(b)(1) (requiring that registrants maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.").

213. Through its incorporation of federal law, Maryland places a duty on Defendants to monitor, detect, investigate, refuse to fill, and report suspicious orders of opioids. 21 C.F.R 1301.74. Distributor Defendants have a non-delegable duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the [DEA] in his area of suspicious orders when discovered by the registrant." 21 C.F.R. § 1301.74(b).

214. Thus, Maryland regulations mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the requisite authority. Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert Defendants to potential problems.

215. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor who observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply – can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual, given the customer's history or its comparison to other customers in the area.

216. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

217. Maryland and federal statutes and regulations reflect a minimum standard of conduct and care below which reasonably prudent manufacturers and distributors should not fall. Together, these laws and industry guidelines make clear that Defendants must possess, and are obligated to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

218. Further, these laws and industry standards make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

219. The FTC has recognized the unique role of Defendants McKesson, Cardinal, and AmerisourceBergen (the "Big Three"). Since their inception, the Big Three have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, the Big Three also offer their pharmacy, or dispensing, customers a broad range of added services. For example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory-carrying costs. The Big Three are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.[95] As a result of their acquisition of a diverse assortment

[95] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.).

of related businesses within the pharmaceutical industry, as well as the range of additional services they offer, the Big Three have a unique insight into the ordering patterns and activities of their dispensing customers.

220. Like the Big Three, Walgreens and Rite Aid are uniquely positioned to know the ordering patterns and activities of their dispensing customers due to their roles as both distributors and national retail pharmacies. As national retail pharmacies, Walgreens and Rite Aid have vertically integrated models, which place them in a unique role, as they have both specific obligations under the CSA and a particular ability to spot, report, and stop filling suspicious orders. National retail pharmacies, like other distributors, are registrants under the CSA 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

221. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

222. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

223. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible as compared to most written prescriptions; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

224. Other signs of diversion can be observed through data that is gathered, consolidated, and analyzed directly by Walgreens and Rite Aid. That data allows national retail pharmacies, like Walgreens and Rite Aid, to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[96] The majority of pharmacies sell these records.[97]

225. According to industry standards, if a pharmacy finds evidence of prescription

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[96] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[97] *Id.* at 389.

diversion, the local Board of Pharmacy and DEA must be contacted.

226. Manufacturing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Manufacturing Defendants to observe the signs of suspicious prescribing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturing Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing that would have alerted them independent of their sales representatives, to suspicious prescribing. These information points gave Manufacturing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under Maryland and federal law.

227. Defendants have a duty to, and are expected to, be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. Defendants breached their duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

ii. Defendants Understood the Importance of Their Reporting and Due Diligence Obligations

228. All Defendants were well aware that they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

229. Recently, Defendant Mallinckrodt admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[98] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

230. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association to which the Big Three (and Manufacturing Defendants) belong, and the National Association of Chain Drug Stores ("NACDS"), where Walgreens sits on the Board of Directors, have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[99] Guidelines established by the HDA also explain that distributors, "[a]t the center of a

[98] https://www.justice.gov/usao-edmi/press-release/file/986026/download

[99] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

sophisticated supply chain. . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[100]

231. The DEA also repeatedly reminded the Defendants of their obligations under federal law, mirrored in and incorporated by Maryland law, to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[101] The Big Three Distributor Defendants have each attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

232. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly. . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for

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[100] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

[101] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[102] The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[103] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[104]

233. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[105] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to

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[102] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[103] *See id.*

[104] *See id.*

[105] *See* 2007 Rannazzisi Letter.

report suspicious orders and "some criteria to use when determining whether an order is suspicious."[106]

ii. Despite Repeated Admonitions, Defendants Have Repeatedly Violated their Obligations

234. Distributor Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

235. Governmental agencies and regulators have confirmed (and in some cases Distributor Defendants have admitted) that Distributor Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.

236. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, McKesson, and Walgreens:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

[106] *See id.*

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On September 30, 2009, the DEA issued an Order to Show Cause against the Walgreens retail facility in San Diego, California.

i. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 Walgreens MOA") with the DEA in relation to its San Diego facility. The MOA provided that "Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations.

j. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

k. On September 14, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Walgreens' Distribution Center in Jupiter, Florida.

l. On June 11, 2013, Walgreens agreed to pay $80 million in civil penalties to resolve the DEA's investigations. It also entered into another Memorandum of Agreement with the DEA in which it acknowledged that its distribution and dispensing practices were not fully consistent with its obligations under the CSA.

237. Both Defendant Cardinal Health and Defendant McKesson have also been fined for violations involving pharmacies or distribution facilities in Maryland. On December 23, 2016, Cardinal Health agreed to pay a $34 million fine to the DEA to settle allegations raised in the February 2, 2012 *Order to Show Cause and Immediate Suspension Order* that it violated the CSA by failing to report suspicious orders sent from its Lakeland, Florida distribution centers to pharmacies in Florida and Maryland.[107]

238. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders, including from its distribution facility in Landover, Maryland. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[108]

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[107] The Settlement also included a related $10 million settlement in New York. *Id.*; Margie Manning, Cardinal Health Agrees to $44 M Settlement in Lakeland, New York Cases, Tampa Bay Business Journal, December 23, 2016.

[108] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

239. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[109] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations . . . at the McKesson Distribution Centers" including the McKesson Distribution Center located in Landover, Maryland. These failures were direct violations of the 2008 McKesson MOA with the DEA. *See supra* ¶ 222(f). Upon information and belief, the McKesson facility located in Landover supplied opioids to the County.

240. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[110] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[111]

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[109] *Id.*

[110] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[111] *Id.*

241. Even the far lesser-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Maryland and three other states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[112]

242. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[113] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[114] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[115] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[116]

243. Further, in a *60 Minutes* interview in the fall of 2017, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat

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[112] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[113] *Id.* (alteration in original).

[114] *Id.* (quoting a March 30, 2015 DEA memo).

[115] *Id.*

[116] *Id.*

they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die. "[117] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[118]

244. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[119] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[120]

245. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. Despite the frequent prior enforcement actions described

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[117] Bill Whitaker, Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

[118] *Id.*

[119] *Id.*

[120] *Id.*

above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

246. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

247. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of only two pages. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—more than 9,500 pills *per day*.

248. Further, as referenced above, Walgreens has also been repeatedly penalized for its illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of Walgreens, including in Maryland.

249. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates

more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

250. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[121]

251. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

252. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[122]

253. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate

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[121] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[122] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities. [123]

254. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[124]

255. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

256. For example, in January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[125]

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[123] *Id.*

[124] *Id.*

[125] *Id.*

257. Rite Aid has also been cited and fined by the DOJ for its failures to comply with CSA requirements. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA. The investigation revealed that from 2004 onwards, Rite Aid had a pattern of non-compliance with the requirements of the CSA and federal regulations, leading to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated, including in Maryland. Rite Aid also failed to notify the DEA of thefts and losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b), including from five pharmacies in Maryland.

258. Manufacturers had knowledge of diversion as well and have failed to comply with their obligations to report and decline suspicious orders, and stop detailing suspicious prescribers. Sales representatives learned that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

259. Moreover, Manufacturing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal

charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[126]

260. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[127] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[128] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

261. Mallinckrodt also failed to report suspicious prescribing. A former Mallinckrodt sales representative reports that he regularly visited a doctor over the course of 5 years. The doctor has now been criminally indicted. During the visits, the representative saw the doctor's office

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[126] Meier, *Pain Killer*.

[127] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

[128] *Id*.

overflowing with patients, some of whom waited for up to 8 hours to see the doctor, and heard them bragging about earning $70,000 from selling prescriptions written by the doctor. Despite having around 300 doctors on his call list, the former sales representative's supervisor at Mallinckrodt instructed the sales representative to spend half of his time with the doctor because of the sales potential due to the doctor's prescribing. The sales representative and his supervisor did not report the doctor because his prescribing was very high, and the company made a lot of money from his prescribing.

262. These examples demonstrate how Manufacturing Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. The goal of the marketing strategy was to increase these Defendants' profits by convincing more doctors to prescribe opioids in higher and higher doses for long term use. Thus, these Defendants did identify doctors who were their most prolific prescribers, but not to determine if their prescribing was suspicious and, if so, report them. Defendants identified these prescribers to market to them and ensure they continued to prescribe more and more of Defendants' opioids.

263. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this

community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[129]

264. But given the closeness with which these Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

H. Defendants Worked Together To Sustain Their Market and Boost Their Profits

265. The Big Three, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock."[130] Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

266. Distributor Defendants had financial incentives from manufacturers to distribute

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[129] Meier, *Pain Killer*, at 179.

[130] *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).

higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits. Of course, increased sales volumes have also resulted in the oversupply of opioids and concurrent increases in addiction, overdose, and criminal diversion across the nation and in Howard County.

267. Upon information and belief, each of the Distributor Defendants also worked together, and with Manufacturing Defendants, through trade or other organizations, such as the HDA, the National Association of Chain Drugstores, and the Pain Care Forum ("PCF"),[131] to safeguard the market for opioids and the distribution of opioids.[132]

268. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.[133] All of the Manufacturing Defendants were members as well.[134]

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[131] The Pain Care Forum is a lobbying organization.

[132] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

[133] https://www.healthcaredistribution.org/about/membership/distributor (H.D. Smith would have been represented by Smith Drug Company, Div. J M Smith Corporation.)

[134] https://www.healthcaredistribution.org/about/membership/manufacturer.

269. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Big Three with the opportunity to work closely with each other and with opioid manufacturers, confidentially, to develop and further their common purpose and interests.

270. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributors advertise these conferences as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[135] The conferences also gave the Distributors and Manufacturing Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[136] The HDA and its conferences were significant opportunities for the Big Three to interact at a high level of leadership.

271. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality

[135] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed on Sept. 14, 2017).

[136] *Id.*

improvement." Participation in this committee includes distributors and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[137]

272. The Distributor Defendants and Manufacturing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" Upon information and belief, the Manufacturing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

273. The Big Three also coordinated with each other and opioid manufacturers in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a

[137] Councils and Committees, Healthcare Distribution Alliance, (accessed on December 11, 2017), available at https://www.healthcaredistribution.org/about/councils-and-committees

decade."[138] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, as is described in this Complaint.

274. Distributor Defendants also worked together through HDA and National Association of Chain Drugstores ("NACDS"). The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Distributor Defendants worked together to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

275. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts to engage in the unlawful sale of prescription opioids.

276. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing

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[138] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

277. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

278. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturing and Distributor Defendants did this through their participation in the PCF, HDA, and the NACDS.

279. Upon information and belief, the Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

I. Defendants Ignored Red Flags Of Abuse and Diversion

280. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database.[139] ARCOS, which stands for Automation of Reports and Consolidated Orders System, tracks controlled substances distribution based on data provided by manufacturers and distributors. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants and Manufacturing Defendants, but has not been disclosed to the public.

281. Yet, publicly available information confirms that Defendants funneled far more opioids into Howard County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Howard County.

282. The Plaintiff's information and belief rests upon the following facts:

(a) distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) The Big Three, Manufacturing Defendants, and Defendant Insys regularly visit pharmacies and/or doctors to promote and provide their products and services, which allows them to observe red flags of diversion. Similarly, Walgreens and Rite Aid have direct access to the transaction data of its chain of retail pharmacies.

(c) The Big Three together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

(d) Walgreens and Rite Aid have been relatedly penalized for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests they are the product of national policies and practices;

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[139] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

(e) Performance metrics and prescription quotas adopted by the national retail pharmacies such as Walgreens and Rite Aid for their retail stores contributed to their failure. The result is both deeply troubling and entirely predictable: opioids flowed out of national retail pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

283. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. Walgreens, for example, had direct access to the prescription rates of its retail pharmacies.

284. Distributors have a duty to know their customers and the communities they serve. Wholesale distributors, such as the Big Three, developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help distributors identify suspicious orders or customers who were likely to divert prescription opioids.[140] The "know your customer" questionnaires informed distributors of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

285. According to testimony by a former Executive Chairman of the Board of Cardinal at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug

[140] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Administration (*available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA,* Purdue Pharma and McGuireWoods LLC, (*available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports, and, as explained above, Walgreens would have had this information from their own pharmacies.

J. Howard County is a High Intensity Drug Trafficking Area Significantly Harmed by the Opioid Epidemic.

286. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Howard County, should have investigated, terminated suspicious orders, and reported potential diversion to law enforcement.

287. In April 2018, two men pled guilty in federal court to operating a pill mill in Howard County. The men operated First Priority Health Care, LLC in Elkridge, Maryland which purported to be a pain management clinic. The clinic distributed oxycodone prescriptionsto "patients" who did not have a legitimate medical need. The two men were reported to have purchased oxycodone pills from fake patients who received prescriptions from the clinic, and then they resold the pills for a profit. They helped the fake patients create false medical records in order to receive oxycodone prescriptions from their clinic. According to the indictment, in one month the clinic would see a minimum of 200 "patients" and distribute 20,000 pills.[141] Upon information and belief, this clinic, and the pharmacies at which the prescriptions from the clinic were filled, would have yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants to an oversupply in the County and to specific instances of diversion.

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[141] https://www.nbcwashington.com/news/local/16-Indicted--in-Maryland-Pill-Mill-Ring-Bust-305359241.html.

288. In addition, the increase in fatal overdoses from prescription overdoses has been widely publicized for years. Between 2016 and 2017, the County experienced a 27.5% increase in fatal opioid overdoses and 29% increase in non-fatal opioid overdoses. The CDC estimates that for every opioid-related death, there are 733 individuals who take opioids for non-medical reasons. Defendants thus had every reason to believe that an overall oversupply and/or illegal diversion was occurring in Howard County.

289. Moreover, Howard County was one of the 9 Maryland local jurisdictions to be labeled as a "high intensity drug trafficking area" ("HIDTA"), which means the area is a critical drug trafficking region of the United States.

290. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Howard County.

K. Defendants Hid Their Lack of Cooperation With Law Enforcement and Falsely Claimed To Be Actively Working To Prevent Diversion

291. When a wholesaler or manufacturer does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

292. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in

2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

293. More generally, the Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone."[142] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[143] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.[144] A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[145]

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[142] Cardinal website, Ethics and Governance, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html.

[143] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[144]Cardinal website, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/community-relations/population-health/rx-drug-misuse-and-abuse.html.

[145] Lenny Bernstein et al., How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job', The Washington Post (Oct. 22,2016), http://wapo.st/2vCRGLt.

294. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.[146] Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[147]

295. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." [148] A company spokeswoman, Lauren Moyer, also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[149]

296. Walgreens also publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription. Citing these efforts, Walgreens promotes itself as committed to

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[146] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

[147] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[148] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[149] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

297. Rite Aid has recently similarly represented itself as a company that is fighting the opioid epidemic. In October 2018, Rite Aid published a press release which stated that it is working with local law enforcement, state and federal agencies, as well as community groups in order to prevent opioid diversion. Rite Aid also claimed to be developing programs which, like Walgreens, would make Naloxone available without a prescription, along with the distribution of packets that would allow for the disposal of opioids, and medication drop-off units.

298. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[150]

> "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

"Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

299. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

[150] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

300. These public statements created the false and misleading impression that the Distributor Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

301. Manufacturing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[151]

302. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

303. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[152] Purdue's statement on "Opioids Corporate Responsibility" likewise

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[151] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[152] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-

states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[153] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[154]

304. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

305. Mallinckrodt made misrepresentations regarding its efforts to fight opioid addiction. Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."[155] The truth, of course, is that Mallinckrodt failed to put in

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with-abuse-deterrent-properties/ .

[153] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/news-media/opioids-corporate-responsibility/ .

[154] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

[155] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders, which supplied far more opioids than were justified and led to diversion of opioids in Howard County and other Counties and states.

306. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

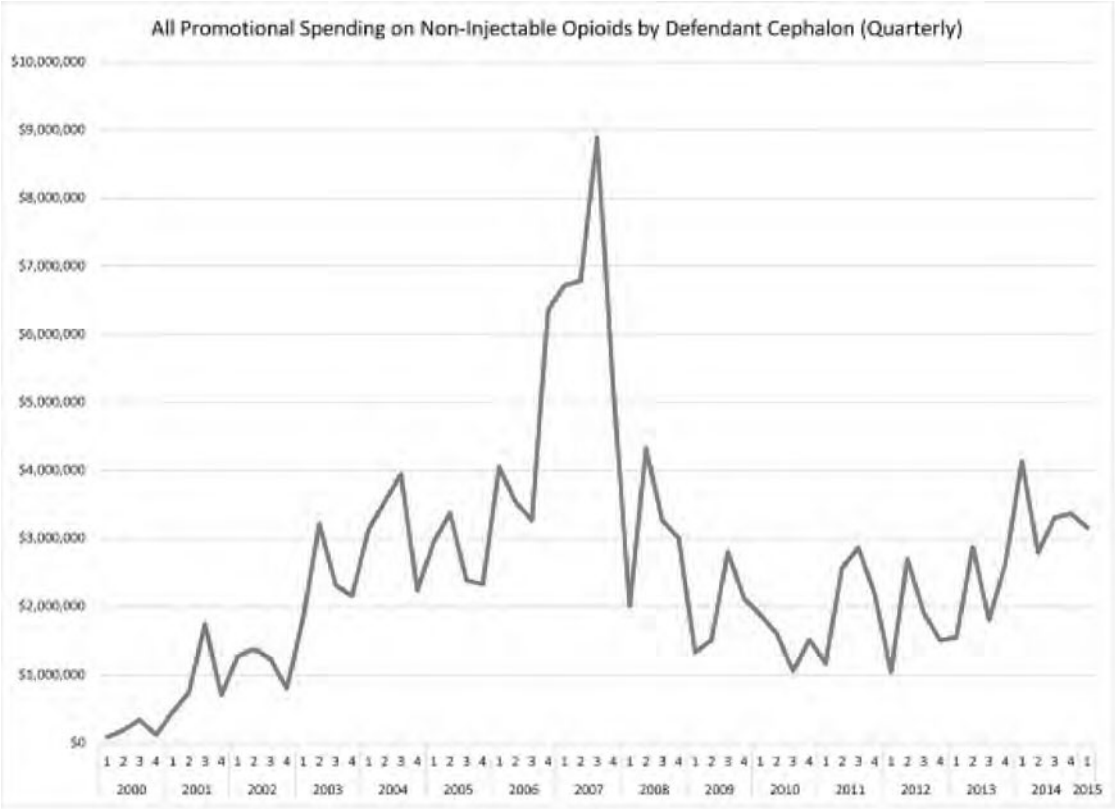
L. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed Howard County and its Residents

307. Manufacturing Defendants' and Defendant Insys' misrepresentations and deceptive conduct prompted Howard County health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing and, in at least the case of Insys, fraudulent activities, Manufacturing Defendants and Defendant Insys overcame barriers to widespread prescribing of opioids for chronic pain. The Distributor Defendants recklessly distributed opioids and failed to meet their regulatory obligations in Maryland.

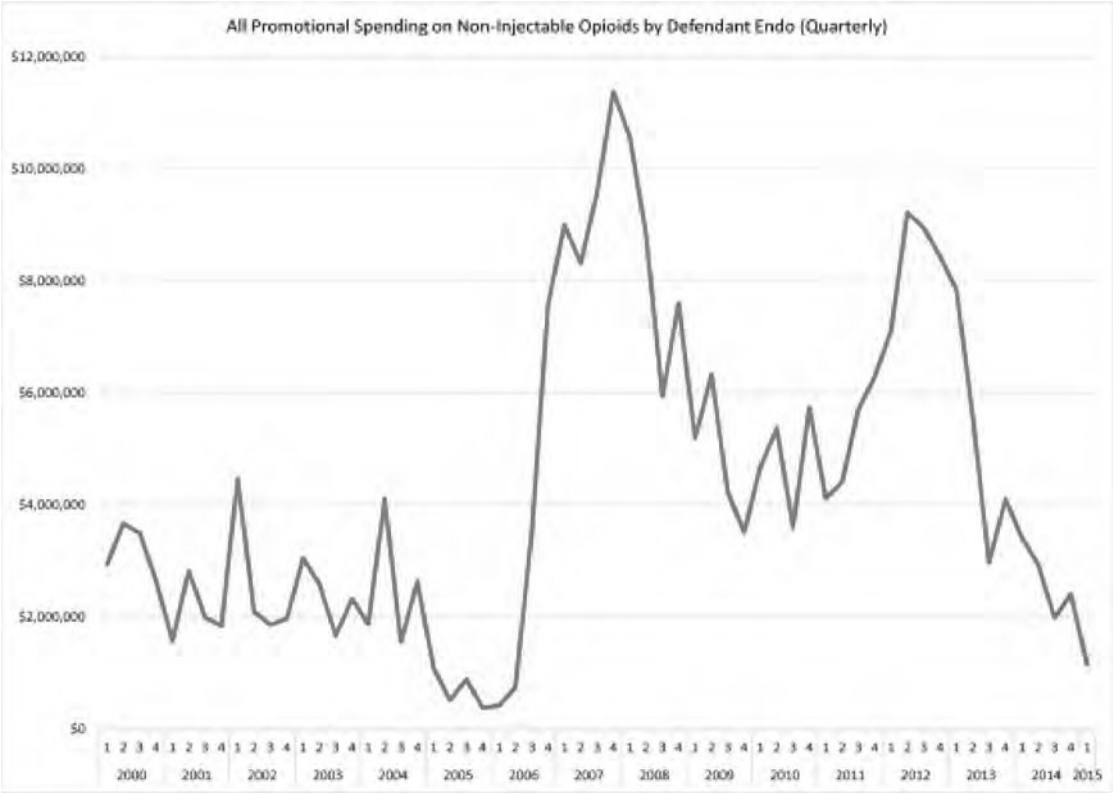
308. Defendants' deceptive marketing and illegal distribution practices substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

309. Manufacturing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

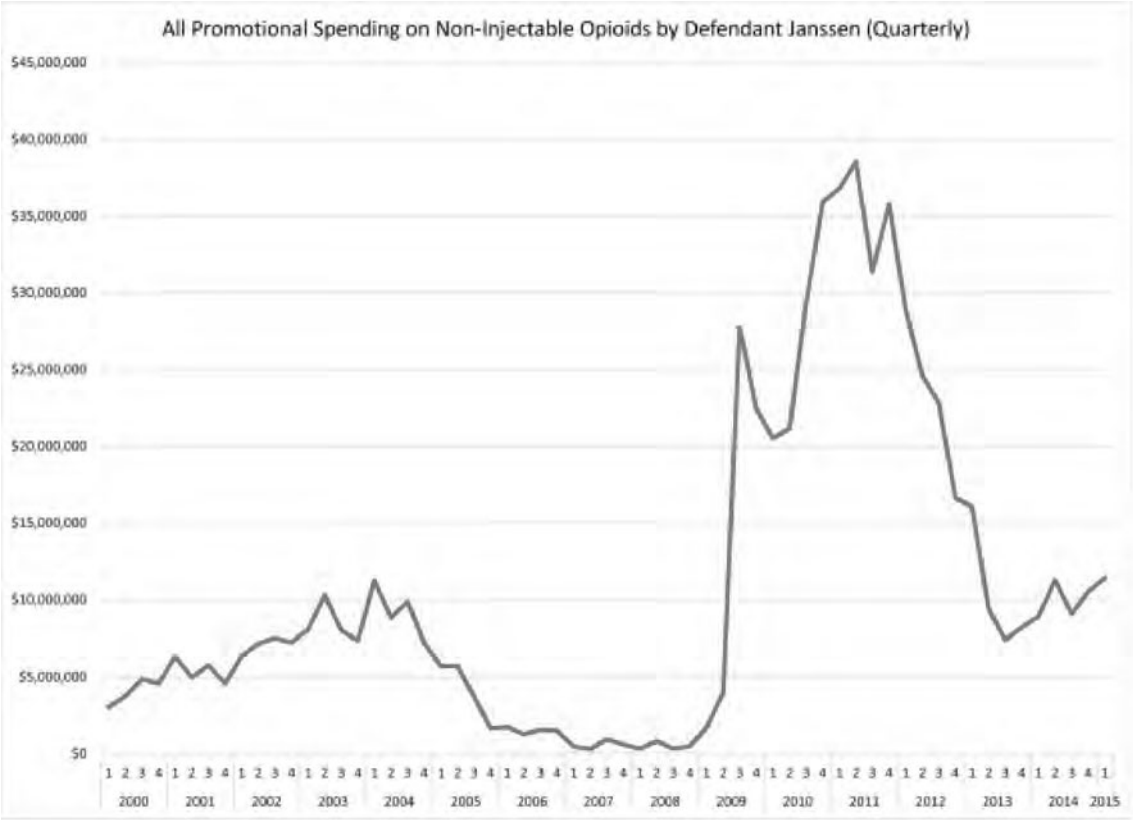
310. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



311. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):

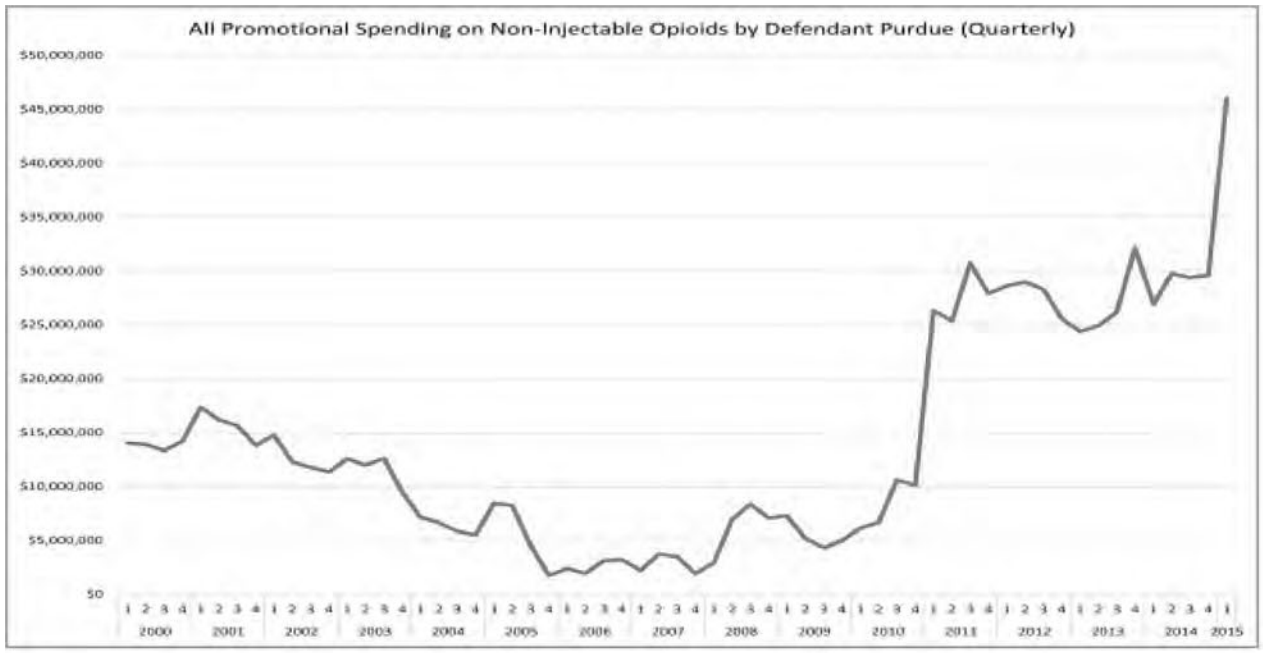


312. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



313.

Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a



total of $110 million that year), and continued to rise through at least 2015.

314. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in Howard County. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[156]

[156] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

315. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[157]

316. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

317. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the

[157] *See* Murthy, *supra* note 2.

CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[158]

318. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[159]

319. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[160] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[161]

M. Howard County Continues to Be Burdened with Significant Expenses as a Result of All Defendants' Malfeasance in Causing the Opioid Epidemic.

320. The County incurs significant expense due to its efforts to curb the opioid crisis. In fiscal year 2019, the County has a budget of nearly $1 million for costs associated with opioids, including general addiction services and opioid administrator salaries. The County will also use $150,000 of Health Department funding for opioid prevention strategies, in addition to $50,000 used in fiscal year 2018. These funds will go towards the establishment of a crisis stabilization center, which will allow County residents to be assessed and recommended for care involving

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[158] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths—United States, 2000–2014*, Am. J. of Transplantation 16.4 (2016): 1323-1327.

[159] Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[160] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[161] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).

opioid use and abuse. The County hopes to open the center in the spring of 2019, and plans to keep it open and available 24 hours a day, 7 days a week. The County plans on hiring a physician, a nurse or nurse practitioner, a social worker, peer recovery support specialists, an intake specialist, and a receptionist to work at the center and help County residents in need of opioid addiction treatment.

321. Howard County has also spent significant funds on opioid prescriptions through its health care plans and workers' compensation program. From January 1, 2011 until January 1, 2018, County funded health insurance and workers compensation plans spent over $1.3 million on opioid prescriptions for County employees.

322. Nationwide, opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses. Many Howard County residents have experienced opioid-related overdoses, and far too many have lost their lives as a consequence. The number of overdoses in Howard County continues to increase. In 2015, there were 18 opioid-related deaths in the County. In 2016, this number more than doubled to 40 opioid-related deaths in the County. Between 2016 and 2017, the County experienced a 27.5% increase in fatal opioid-related overdoes and a 29% increase in non-fatal opioid-related overdoses. Between January 1, 2017 and April 1, 2017 there were 39 non-fatal opioid-related overdoses. In the same time frame in 2018, there were 56 non-fatal opioid-related overdoses in the County. As of October 9, 2018, there were 179 opioid-related overdoses in the County, including 33 fatal overdoses. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive.

323. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

324. The overprescribing of opioids causes an increase in additional medical conditions. A growing number of people need medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by the *Washington Post*, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effect medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves.

325. The deceptive marketing and overprescribing of opioids also has a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse.[162] Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin.[163] However, according to the CDC

[162] U.S. Pharmacist, Legitimate Opioid Use Prior to High School Graduation Increase Abuse Risk, available at https://www.uspharmacist.com/article/legitimate-opioid-use-prior-to-high-school-graduation-increases-abuse-risk.

[163] National Institute of Health, *Prescription Opioid Use is a Risk Factor for Heroin Use,* available at https://www.drugabuse.gov/publications/research-reports/relationship-between-

Guidelines, there has been a significant increase in the prescribing of opioids to adolescents and children for headaches and injuries.[164]

326. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

327. In 2015, there were 1,419 cases of NAS in Maryland—an average of 118 affected babies per month. The average hospital stay for a newborn with NAS in Maryland is 26 days. The number of babies born with alcohol or drugs in their system increased 56.6 percent between 2008 and 2017 in Maryland. The majority of these babies were exposed to prescription painkillers or heroin, while others have methadone or buprenorphine in their systems due to the mothers' attempts to overcome opioid addiction.

328. Contrary to Defendants' misrepresentations, most of the illicit opioid use originates from prescribed opioids. It has been estimated that 60% of the opioids that are abused come,

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prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use.

[164] CDC Guideline for Prescribing Opioids for Chronic Pain – United Stated, 2016, *Morbidity and Mortality Weekly Report* 3 (March 18, 2016)..

directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

329. Those who are addicted to prescription opioid painkillers are 40 times more likely to become addicted to heroin. Prescription opioids, at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. Not surprisingly, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

330. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury. Prosecutors from the Office of the State's Attorney for Howard County have noted that dealers in the County will buy entire prescriptions from patients, or from those committing prescription fraud, for approximately a quarter of the price that they sell the drugs for on the street. In August 2017, the Howard County Police Department arrested a man for selling opioids, including oxycodone and buprenorphine, along with other drugs, from his car. Additionally, during the search of the individual's car, police found fentanyl, a synthetic opioid, discussed further below. In December 2017, a Howard County resident was arrested for distribution of heroin and other drugs. During a search of his home incident to his arrest, Howard County officers found more than 100 capsules of suspected heroin, along with other drugs, drug packaging materials, a loaded handgun, three cell phones, and cash.

331. According to the County's Police Department's Vice and Narcotics Division, opioids that are illegally used and diverted in the County are from street-level, mid-to-high level distributors and pill mills. The Division has received information that some County residents

suffering from opioid use disorders visit specific dealers on a regular basis, or doctors who they know will prescribe opioids. Due to the close proximity to Baltimore City, some also travel there to purchase heroin. County agencies are continually working to identify and remove drug suppliers from County streets to help fight the opioid crisis.

332. The Howard County State's Attorney's Office, which is funded by County government rather than the State of Maryland, is heavily involved in working to fight the opioid epidemic. Over the last five years, the nature and depth of its investigations into the distribution of opioids has increased significantly. From January 2017 through August 2018, the State's Attorney's Office drug unit spent approximately two hundred hours on opioid investigations. Due to the increase in opioid-related prosecutions, the three County felony drug prosecutors now only handle opioid-related cases; additional criminal cases must be taken on by other County prosecutors.

333. The Howard County Department of Corrections is also on the front lines of the opioid epidemic in the County. Its medical department treated 351 inmates in fiscal year 2018 for opioid detoxification. Additionally, during the same time frame, the Detention Center had 223 inmates participate in the substance use disorder program, where 50% of participants have a primary diagnosis of opiate use disorder. The treatment offered at the detention center is provided and paid for by the County's Health Department. The Health Department also provides Narcan, the antidote to opioid overdose, to the Department of Corrections to assist the inmates if needed.

334. Fentanyl is a relatively recent, even more deadly problem stemming from the prescription opioid epidemic. Fentanyl is a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into communities across the country. Howard County prosecutors have noticed an increase in criminal cases involving the combination

of heroin and fentanyl. In the first six months of 2017, 21 of 28 opioid-related deaths of County residents involved fentanyl.

335. In light of this crippling epidemic, Howard County has instituted a number of cutting edge programs aimed at curbing addiction and abuse. In early 2018, Howard County offered opioid overdose and Narcan training to County residents, County employees, and staff and inmates of the Howard County Detention Center. The County has also placed Narcan in different County buildings, and has increased the Narcan supply of first responders. Additionally, the Howard County's Sheriff's Office, which is funded by Howard County, trains all of its Deputies and Security Officers on the administration of naloxone, and as of August 2018, fifty-seven of the Office's personnel had received the training. The Sheriff's Office also ensures that each new Deputy and Security Officer receive the training when hired. In 2017, the Office spent $3,000 to provide its personnel with naloxone, its delivery systems, and carrying casts.

336. The extensive training the Sheriff's Office provides is necessary due to the breadth of the opioid crisis. For example, in December of 2017, deputies encountered a person awaiting trial in the County's Circuit Courthouse who was suffering from the side effects of an opioid overdose, among other things. The deputies administered naloxone and monitored him until the Department of Fire and Rescue Services arrived to take him to the hospital.

337. The County has also created educational programs to inform County residents about opioid abuse and prevention. For example, in April 2018 it launched a social media campaign aimed at opioid and other drug and alcohol prevention through social media blasts. The County also held educational forums with adults and with a teen advisory council, and sponsored educational programs through health and community fairs.

338. In addition, the County has undertaken educational programs aimed at prescribers regarding opioid use and prescribing guidelines. These efforts have included mailings regarding opioids which contained CDC check-lists, and tip sheets on opioids which were sent on a quarterly-basis to prescribers within the County.

339. The County has placed medication drop boxes inside of police stations, allowing County residents to dispose of their prescription drugs, including opioids, safely. The County also provides education to the public on how to safely store prescription drugs and where to locate the medication drop boxes. Additionally, the County holds a Drug Take Back Day twice a year in which the County collects unused prescription medications, including opioids. During the drug take back day held in April 2017, the County collected 1,126 pounds of prescription drugs. The County has also cultivated relationships with pharmacies within the County which allows pharmacies to refer residents to the Howard County DrugFree program for recommendations on safe medication storage and disposal.

340. The County is also working to combat teen and adolescent opioid abuse. The County provides information about sports injuries and prescription pain medications during high school athletic parent nights. It is also planning an evidence-based program that is aimed at helping parents of adolescents learn skills to prevent future substance abuse. The County is currently developing a "Mental Health First Aid" program, which is an 8-hour certification course aimed at County teachers, which discusses risk factors for substance abuse disorders, among other topics.

341. County agencies, such as the Department of Health, and the County courts have also taken substantial steps to curb the opioid crisis in the County. The Drug and DUI courts provide case management and treatment coordination for individuals who are referred by Drug and DUI court employees. Additionally, the Howard County General Hospital currently has a full-

time social worker in the Emergency Department who identifies patients who are at risk for opioid addiction. The social worker refers these patients to residential rehabilitation centers throughout Maryland and the country. If the patient is already enrolled in an outpatient treatment program, the hospital works with the program to ensure that proper medical care continues.

342. The County recently launched a new website, www.HoCoOpioidHelp.com, which assists County residents in finding information on opioids. Such information includes treatment resources, training, and other programs.

343. As of November 2017, the County had 13 outpatient treatment programs providing services for residents with substance use disorder, including opioid use disorder. In addition, the County spent $100,000 in fiscal year 2018 to create a study regarding program requirements for a 50 to 60 bed inpatient facility to serve County residents. The study includes expert analysis from a treatment provider who has managed and operated treatment facilities, who will produce a facility plan for the center's development. The County spent an additional $100,000 in fiscal year 2018 to relocate a residential, low-intensity treatment facility for men, which is owned by the County. The new facility is set to open this month. The budget for fiscal year 2019 was also increased significantly to provide funding for a recovery house for County residents who are impacted by opioids, and an additional $150,000 was included in the budget for on-going County Health Department opioid outreach activities.

344. The Howard County Police Department has incurred substantial expenses due to the opioid crisis in the County. From January 1, 2018 until July 31, 2018, the Department spent just under $230,000 on costs associated with opioid use disorders, including but not limited to, officer dispatches for non-fatal and fatal overdoses, overdose death investigations, crime scene

processing for death investigations, drug analysis for death investigations, equipping officers with Narcan, and disposal costs.

345. The burdens imposed on Howard County are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Defendants' illegal actions.

N. Defendants Fraudulently Concealed Their Misconduct

346. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants and Defendant Insys of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

347. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Purdue, Endo, Teva, Mallinckrodt, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish

the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, Mallinckrodt, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

348. Manufacturing Defendants and Defendant Insys successfully concealed from the medical community, patients, and Howard County facts sufficient to arouse suspicion of the claims that Howard County now asserts. Howard County did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

349. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to publicly release the information they have provided to the DEA for the ARCOS database, which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

350. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and pharmacy orders.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

353. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

354. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of the public in Howard County by their production, promotion, marketing, distribution, and sale of opioids for use by residents of Howard County.

355. Defendants' acts and omissions offend, significantly and unreasonably interfere with, and cause damage to the public rights common to all, such as the public health, public safety, public peace, and the public comfort. Defendants had control over their conduct in Howard County and that conduct has had an adverse effect on the public right. The public nuisance caused by Defendants has significantly harmed the County and a considerable number of County residents.

356. Defendants' conduct is unreasonable.

357. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

358. Manufacturing Defendants and Defendant Insys knew or should have known that their promotion of opioids was false and misleading and that their deceptive marketing schemes and/or other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

359. All Defendants knew or should have known that distributing or selling opioids in ways that facilitated and encouraged their flow into the illegal secondary market, distributing or selling opioids without maintaining effective controls against diversion, choosing not to stop or

suspend shipments of suspicious orders, choosing not to report suspicious prescribing, and distributing or selling opioids to pill mills when Defendants knew or should have known the opioids were being prescribed by pill mills, would create or assist in the creation of a public nuisance.

360. Defendants have created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, and public comfort and offends the moral standards of the community.

361. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in the complaint.

362. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Howard County. Manufacturing Defendants' and Defendant Insys' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe. Moreover, by failing to report or cease supplying known pill mills in the County, Defendants exacerbated the opioid crisis in the County, and failed to limit its reach.

363. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

364. The County suffered special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred substantial costs from investigating, monitoring, treating, policing, and attempting to remediate the opioid epidemic.

365. The public nuisance – i.e. the opioid epidemic - created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

WHEREFORE, The County demands judgment in its favor against the Defendants for compensatory damages in an amount exceeding $75,000, and injunctive relief together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT II
Maryland False Claims Act, Md. Code Ann., Gen. Prov. §8-101 - § 8-111
(Against Manufacturing Defendants and Defendant Insys)

366. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

367. Maryland General Provisions § 8-102 provides that:

> (b) A person may not:
> (1) knowingly present or cause to be presented a false or fraudulent claim for payment or approval; (2) knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim; (3) conspire to commit a violation under this title; …or (9) knowingly make any other false or fraudulent claim against a governmental entity.

368. Pursuant to Maryland General Provisions § 8-101(e), the County is a "governmental entity" as that term is used in §8-102.

369. Manufacturing Defendants' practices, as described in this Complaint, violated Maryland General Provisions § 8-102. Defendants, through their deceptive marketing of opioids

for chronic pain, and/or intentional overprescribing of opioids knowingly made, or caused to be made, false or fraudulent claims to the County and/or its agents; knowingly made or caused to be made or used false statements material to such claims; and conspired to cause such false or fraudulent claims and statements to be made to the County and/or its agents.

370. Upon information and belief, Defendants knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading or contained material omissions and were made for the purpose of getting the County to pay for opioids for long-term treatment of chronic pain. In addition, Manufacturing Defendants and Defendant Insys knew, deliberately ignored, or recklessly disregarded, that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

371. Manufacturing Defendants knew that the doctors, pharmacists, other health care providers, and/or agents of the County to whom they deceptively marketed prescription opioids had treated and would continue to treat patients whose prescription costs were paid or reimbursed by the County health plan and County workers' compensation plan.

372. Manufacturing Defendants' and, upon information and belief, Defendant Insys' scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the County in an attempt to obtain payment from public funds.

373. Defendants knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of their actions, governments such as the County would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Defendants' fraud. Indeed, Defendants acted to maximize their reimbursements from these

third-party payors.

374. Defendants' misrepresentations and omissions were material because if the County had known of the false statements and/or false claims, the County would have undertaken efforts to avoid its payment of false claims.

375. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic pain were paid by the County.

376. By virtue of the above-described acts, Defendants knowingly and willfully made, used or caused to be made, false statements or representations and deliberately concealed material facts, to induce the County to provide benefits, payments, or reimbursements.

377. The County has paid, and continues to pay for reasons explained above, claims that would not be paid but for Defendants' false claims, statements, or representations of material fact, or omission of material facts.

378. But for Defendants' false statements, the false claims at issue would not have been submitted for payment and would not have been paid by the County.

379. Because Manufacturing Defendants' unbranded marketing caused doctors to prescribe and the County to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims as well.

380. By reason of Defendants' unlawful acts, the County has been damaged, and continues to be damaged in a substantial amount to be determined at trial.

WHEREFORE the County demands judgment in its favor against the Defendants in an amount in excess of $75,000, and for civil penalties and treble damages pursuant to Maryland

General Provisions § 8-102(c) together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT III
Maryland Consumer Protection Act
Md. Code Ann., Com. Law §13-101 - §13-501
(Against Manufacturing Defendants and Defendant Insys)

381. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

382. Maryland's Consumer Protection Act ("CPA") provides:

> A person may not engage in any unfair or deceptive trade practice, as defined in this subtitle or as further defined by the Division, in: (1) the sale, lease, rental, loan, or bailment of any consumer goods, realty or customer services; [or] (2) the offer for sale, lease, rental, loan, or bailment of consumer goods, consumer realty, or consumer services" Md. Code Ann., Com. Law § 13-303

383. The CPA further states

> Unfair or deceptive trade practices include any (1) false, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers; (2) Representation that (i) Consumer goods…or consumer services have a characteristic…use, [or] benefit…which they do not have;…(3) Failure to state a material fact if the failure deceives or tends to deceive;…(9) Deception, fraud, misrepresentation, or knowing concealment…or omission of any material fact with the intent that a consumer rely on the same in connection with (i) the promotion or sale of any consumer goods. Md. Code Ann., Com. Law § 13-301

384. Manufacturing Defendants and Defendant Insys have violated Maryland's CPA because they engaged in unfair or deceptive trade practices, including deception, fraud, misrepresentation, or the knowing concealment or omission of material facts in the sale and promotion of a consumer good.

385. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturing Defendants and Defendant Insys have engaged in misrepresentations, deception, and knowing omissions of material fact.

386. Specifically, misrepresentations include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Purdue's claims that OxyContin provides a full 12 hours of pain relief;

j. Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain.

387. By engaging in the acts and practices alleged herein, these Defendants omitted

material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h. Manufacturing Defendants and Defendant Insys failed to report suspicious prescribers; and

i. Insys' use of kickback and insurance fraud schemes.

388. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

389. Defendant Insys' statements that Subsys was appropriate for treatment of non-cancer pain were false and unsupported by scientific evidence.

390. Howard County, as a legal entity, is part of the broad class of persons that may avail themselves of a remedy under Md. Code Ann., Com. Law § 13-101(h).

391. The County has been injured as a direct and proximate result of Manufacturing Defendants' and Defendant Insys' violations of the Consumer Protection Act as alleged in this Complaint.

392. Had the County known that these Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, or of Insys' kickback and insurance fraud schemes, the County would have undertaken efforts to avoid payments of related claims.

393. The County has suffered injury and loss as a result of Defendants' acts and practices alleged in this Complaint.

WHEREFORE, the County demands judgment in its favor against the Defendants in an amount in excess of $75,000 for damages pursuant to Maryland Code Ann., Com. Law § 13-101, et seq. together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT IV
Howard County Consumer Protection Ordinance
Howard County Code of Ordinances, §17.400 *et seq.*
(Against Manufacturing Defendants and Defendant Insys)

394. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

395. Howard County's Consumer Protection Ordinance ("CPO") provides: "It shall be unlawful for any merchant to engage in a deceptive or unfair practice with respect to any consumer whether or not any consumer has, in fact, been misled, deceived or damaged thereby." Howard Co. Ord. § 17.403(a).

396. The CPO further states:

> Deceptive or unfair trade practices include, but are not limited to:

> (1) representations that merchandise, goods or services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have . . .
> (5) A misrepresentation as to a material fact which has a tendency to mislead . . .
> (6) The failure to state a material fact, if such failure deceives or tends to deceive . . .
> (14) Any deception, fraud, false pretense, false premise, misrepresentation or the knowing concealment, suppression or omission of any material fact with the intent that consumers rely upon such concealment, suppression or omission in connection with the sale or advertisement of any merchandise or goods or with the subsequent performance of services whether or not any person has, in fact, been misled deceived or damaged thereby. *Id.*

397. Manufacturing Defendants and Defendant Insys have violated Howard County's CPO because they engaged in unfair or deceptive trade practices, including deception, fraud, misrepresentation, or the knowing concealment, suppression, or omission of material facts in the sale or advertisement of merchandise or goods.

398. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturing Defendants and Defendant Insys have engaged in misrepresentations, deception, and knowing concealment, suppression, or omissions of material fact.

399. Specifically, misrepresentations include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Purdue's claims that OxyContin provides a full 12 hours of pain relief;

j. Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion;

k. Teva's claims that Actiq and Fentora were appropriate for treatment of non-cancer pain; and

l.

m. Insys' claims that Subsys was appropriate for treatment of non-cancer pain.

400. By engaging in the acts and practices alleged herein, these Defendants omitted material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d.

e. exaggerating the risks of competing products, such as NSAIDs, while downplaying or omitting the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in

the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

f. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

g. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

h. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

i. Manufacturing Defendants and Defendant Insys failed to report suspicious prescribers; and

j. Insys' use of kickback and insurance fraud schemes.

401. The Consumer Protection Administrator has referred this matter to the Howard County Office of Law. The County has standing to bring an action against Manufacturing Defendants and Defendant Insys for injunctive relief and for penalties for each violation of the CPO.

WHEREFORE, the County demands judgment in its favor against the Manufacturing Defendants and Defendant Insys for injunctive relief pursuant to § 17.405, for penalties pursuant to § 17.412(b), and for such other relief as this Court deems just and appropriate. In compliance with Maryland Rule 2-305, the County pleads that the monetary judgment demanded exceeds $75,000.

COUNT V
Fraudulent Misrepresentation
(Against Manufacturing Defendants and Defendant Insys)

402. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

403. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

404. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturing Defendants and Defendant Insys have engaged in misrepresentations and knowing omissions of material fact.

405. Specifically, misrepresentations or omissions include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain.

406. By engaging in the acts and practices alleged herein, Defendants omitted material facts that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h. Manufacturing Defendants and Defendant Insys failed to report suspicious prescribers;

i. Insys' use of kickback and insurance fraud schemes; and

j. Subsys is not approved, appropriate, or safe and effective for treatment of non-cancer pain.

407. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and not supported by or contrary to the scientific evidence.

408. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead County prescribers and consumers.

409. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

410. Defendants intended that the County and its residents would rely on their misrepresentations and omissions, knew that the County and its residents would rely on their misrepresentations, and that such reliance would cause the County to suffer loss.

411. Healthcare providers and residents in the County reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the County and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

412. Had the County known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, or of Insys' kickback and insurance fraud schemes the County would have undertaken efforts to avoid payments of related claims.

413. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the County suffered actual pecuniary damage.

414. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the County seeks all legal and equitable relief as allowed by law, including judgment in excess of $75,0000, injunctive relief, compensatory and punitive damages, and all

damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VI
Negligent Misrepresentation
(Against Manufacturing Defendants and Defendant Insys)

415. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

416. Manufacturing Defendants and Defendant Insys, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

417. Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs in the County.

418. Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain, while understating their very serious risks, including the risk of addiction.

419. These false statements included but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life; Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

h. Purdue's claims OxyContin provides a full 12 hours of pain relief;

i. Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

j. Insys' claims that Subsys was appropriate for treatment of non-cancer pain.

420. Defendants intended that the County and its residents would rely on their misrepresentations and omissions, knew that the County and its residents would rely on their misrepresentations, and that such reliance would cause the County to suffer loss.

421. Healthcare providers and residents in the County reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the County and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

422. Had the County known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, or of Insys' kickback and insurance fraud schemes the County would have undertaken efforts to avoid payments of related claims.

423. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the County suffered actual pecuniary damage.

424. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the County seeks all legal and equitable relief as allowed by law, including judgment in excess of $75,000, injunctive relief, compensatory and punitive damages, and all

damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VII
Negligence
(Against Manufacturing Defendants, Defendant Insys, and Distributor Defendants)

425. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

426. Under Maryland law, to establish actionable negligence, the County must show, in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such elements exist here.

427. Manufacturing Defendants, Defendant Insys, and Distributor Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in Howard County.

428. Manufacturing Defendants, Defendant Insys, and Distributor Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

429. Manufacturing Defendants, Defendant Insys, and Distributor Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility vis-a-vis the County. Their duty cannot be delegated.

430. In addition, Manufacturing and Distributor Defendants and Defendant Insys each had a duty under Maryland law, which incorporates the federal Controlled Substances Act, to

maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

431. Upon information and belief, each of these Defendants repeatedly breached its duties.

432. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

433. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the County's communities.

434. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of Maryland law for Manufacturing Defendants, Defendant Insys, and Distributor Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

435. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively marketing highly addictive opioids for chronic pain by misrepresenting the risks and benefits of such use would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction

that was foreseeable to the Manufacturing Defendants and Defendant Insys. Reasonably prudent manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

436. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

437. The County seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Manufacturing Defendants, Defendant Insys, and Distributor Defendants. It does not seek damages which may have been suffered by individual citizens of the County for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Manufacturing Defendants, Defendant Insys, and Distributor Defendants.

438. These Defendants breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the County.

439. The misconduct alleged in this case is ongoing and persistent.

WHEREFORE, the County seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including judgment in excess of $75,000, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Manufacturing Defendants, Defendant Insys, and Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VIII

Gross Negligence
(Against Manufacturing Defendants, Defendant Insys, and Distributor Defendants)

440. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

441. Under Maryland law, to establish actionable negligence, the County must show, in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. To establish gross negligence, the County must show that Defendants acted with wanton and reckless disregard for others. All such elements exist here.

442. Manufacturing Defendants, Defendant Insys, and Distributor Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in Howard County.

443. Manufacturing Defendants, Defendant Insys, and Distributor Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

444. Manufacturing Defendants, Defendant Insys, and Distributor Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility vis a vis Plaintiff. Their duty cannot be delegated.

445. In addition, Manufacturing Defendants, Defendant Insys, and Distributor Defendants each had a duty under, Maryland law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report

suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

446. Upon information and belief, each of these Defendants repeatedly and intentionally breached its duties.

447. Manufacturing Defendants, Defendant Insys, and Distributor Defendants acted with wanton and reckless disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

448. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

449. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the County's communities.

450. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of Maryland law for Manufacturing Defendants, Defendant Insys, and Distributor Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

451. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain by misrepresenting the risks and

benefits of such use would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturing Defendants and Defendant Insys. Reasonably prudent manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

452. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

453. The County seeks economic losses (direct, incidental, or consequential pecuniary losses) and punitive damages resulting from the gross negligence of Manufacturing Defendants, Defendant Insys, and Distributor Defendants. The County does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused these Defendants' actions.

454. Manufacturing and Distributor Defendants conduct as described in this complaint constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the County, and also implies a thoughtless disregard of the consequences without the exertion of any effort to avoid them. Manufacturing and Distributor Defendants have acted wantonly and willfully by inflicting injury

intentionally or, alternatively, they have been utterly indifferent to the rights of others, including the County, that they acted as if such rights did not exist.

455. Manufacturing and Distributor Defendants conduct as described in this Count demonstrates wanton and willful disregard for others, including the County, and justifies an award of punitive damages.

456. These Defendants breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the County.

457. The misconduct alleged in this case is ongoing and persistent.

WHEREFORE, the County seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including judgment in excess of $75,000, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Manufacturing and Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT IX
Unjust Enrichment
(Against All Defendants)

458. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

459. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the County.

460. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

461. The County has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

462. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

463. These expenditures have helped sustain Defendants' businesses.

464. The County has conferred a benefit upon Defendants by paying for the cost of the harms caused by Defendants' improper marketing and distribution practices.

465. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

466. The County has paid for the cost of the harms caused by Defendants' improper marketing and distribution practices, and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Manufacturing Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, all Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification.

467. Defendants have unjustly retained benefits to the detriment of the County, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

468. Defendants' misconduct alleged in this case is ongoing and persistent.

469. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence.

470. The County has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

WHEREFORE, the County seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable. In compliance with Maryland Rule 2-305, the County pleads that the monetary judgment demanded exceeds $75,000.

JURY DEMAND

WHEREFORE, Howard County demands a trial by jury as to all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Howard County, Maryland requests the following relief:

a. A finding that by the acts alleged herein, Defendants violated the Maryland Consumer Protection Act, Md. Code Ann., Com. Law §13-101, *et seq.*;

b. A finding that by the acts alleged herein, Defendants violated the Howard County Consumer Protection Ordinance, Howard County Code of Ordinances, §17.400 *et seq.;*

c. A finding that, by the acts alleged herein, Defendants violated the Maryland False Claims Act, Md. Code Ann., Gen. Prov. §8-101 *et seq.*;

d. An award of three times the County's actual damages under Md. Code Ann., Gen. Prov. § 8-101 *et seq.*;

e. A finding that by the acts alleged herein, Defendants have created a public nuisance;

f. For an injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

g. For an order directing Defendants to abate and pay damages for the public nuisance;

h. For a finding that Defendants were negligent and grossly negligent;

i. For compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

j. For punitive damages;

k. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

l. For costs, filing fees, pre-and postjudgment interest, and attorney's fees; and

m. For all other and further relief to which this Court finds it is entitled.

DATED: May 17, 2019

Howard County, Maryland

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Maryland Rule 1-313 Certification

Pursuant to Maryland Rule 1-313, I hereby certify that I am admitted to practice law within the State of Maryland.

Dated: May 17, 2019

/s/ Jeffrey Nelson
Jeffrey Nelson

/s/ Jonathan P. Novak
Jonathan P. Novak